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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/596,194 | 06/16/2000 | Susan J. Kirst | 10147-25 (MBIO99-054) | 2288 |

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| EXAMINER | |
|---|---|
| TAYLOR, JANELL E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 09/19/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/596,194 | Kirst et al. | |
| | Examiner | Art Unit | |
| | Janell Cleveland Taylor | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-7,16-18,24-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,16-18,24-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

## DETAILED ACTION

*The following rejection is **FINAL.** Any rejection not reiterated is withdrawn. A Response to Arguments section follows.*

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the fully disclosed SEQ ID NOS, as well as some larger fragments, and complements thereof, does not reasonably provide enablement for any fragment of any size which may selectively hybridize to the nucleic acids of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. In particular, the way claim 18 is presently worded, any size fragment capable of hybridizing to the sequences of those in claim 1 is claimed. Although the claim states that the fragment "specifically hybridizes" to the target, this does not mean that the fragment hybridizes over its entire length. In other words, it would have been possible that the fragment hybridized only to the last few bases of the target, and had a large "overhang", which did not hybridize at all. This even may have occurred in spite of the hybridization conditions given in the claim, or the fact that it "selectively hybridizes", which means that it would hybridize selectively to the target, but not necessarily over its full length. The specification provides no guidance for

how to make these fragments, or how to use these fragments in a kit. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the specific and complete SEQ ID NOS given above, the skilled artisan cannot envision the detailed chemical structure of *fragments* of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can

clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only the specific SEQ ID NOS given above, not the complementary fragments, meet the written description provision of 35 USC 112, first paragraph.

2. Claims 1, 3-7, 16-18, and 24-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The isolated nucleic acids of the claims include any sequence having at least 90% identity to the sequence found in SEQ ID NO: 59, 60, 61, and 63. Since the claims do not include any *functional limitation*, allelic variants which have different functions from that of the stated sequences are included in the breadth of this claim. The specification has taught only SEQ ID NOS 59-63. The specification has not, however, conveyed that at the time of filing applicants were in possession of a representative number of nucleic acid molecules having the property of having any level of sequence complementarity over any portion of SEQ ID NOS: 59-63. It is noted that this aspect of the rejection may be overcome by amendment of the claims to recite a nucleotide sequence fully complementary to any of the nucleotide sequences listed. Furthermore, the claims as written include nucleic acid molecules having 90% or greater identity to the given nucleotide sequences, and large fragments of the sequence (such as 400 bases). A *functional activity* for the nucleic acid molecule itself is not set forth in the claims. Accordingly, the claims are inclusive of nucleic acid molecules which are allelic variants and which encode for proteins lacking the functional activity of TANGO 332. The specification has not identified any allelic variants and which encode for proteins lacking the functional activities of TANGO 332. The specification has not identified any allelic variants of TANGO 332 having biological activities distinct from wild-type protein. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The structure and

function of one molecule does not provide guidance as to the structure and function of other molecules. This part of the rejection may be overcome by reciting that the nucleic acid molecules code for a polypeptide which retains the functional activity of the TANGO 332 molecule.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "an adequate written description of DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed invention." The limited information provided in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of a full length genomic sequence encoding allelic variants of TANGO 332 having any functional activity, or of the broad genus of nucleic acids having any level of sequence complementarity with SEQ ID NOS: 59-63. Therefore, the written description requirement has not been satisfied for the claims are they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 USC 112, 1st Paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111.

***Response to Arguments***

Applicant's arguments filed July 8, 2002 have been fully considered but they are not persuasive. Applicant has first traversed the rejection of claim 18 under 35 U.S.C. 112, first paragraph. Applicant states that claim 18 has been amended to recite that the compound which selectively hybridizes with the nucleic acid of claim 1 comprises a polynucleotide that hybridizes under specifically-recited hybridization conditions. However, although the claim states that the fragment "specifically hybridizes" to the target, this does not mean that the fragment hybridizes over its entire length. In other words, it would have been possible that the fragment hybridized only to the last few bases of the target, and had a large "overhang", which did not hybridize at all. This event may have occurred in spite of the hybridization conditions given in the claim, or the fact that it "selectively hybridizes", which means that it would hybridize selectively to the target, but not necessarily over its full length. The specification provides no guidance for how to make these fragments, or how to use these fragments in a kit. The specification provides insufficient written description to support the genus encompassed by the claim. Applicant also states that the case law cited was inappropriate because "the cases cited by the Examiner generally deal with situations in which molecules of unknown structure were claimed." However, this is the case in the instant claim as well, as there may be an undefined portion of the nucleic acid which is not hybridizing over its entire length.

Applicant asserts that the rejection of claims 1, 3-7, 16-18, and 24-36 in regards to the recitation of TANGO 332 activity are inappropriate. Applicant argues that the

claimed nucleic acid molecules recited are useful not only for encoding functional TANGO 332 proteins, but also may be useful as probes or primers among other uses. However, absent the teaching of the entire length of the sequence without functional language, one of ordinary skill in the art cannot envision every possible sequence that may exist as *fragments* of the given SEQ ID NOS. Accordingly, the claims are inclusive of nucleic acid molecules which are allelic variants and which encode for proteins lacking the functional activity of TANGO 332, and **are not identified by the specification**. The specification has not identified any allelic variants, **by structure,** which encode for proteins lacking the functional activities of TANGO 332. The specification has not identified any allelic variants of TANGO 332 having biological activities distinct from wild-type protein. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

September 10, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600